

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

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MARK BROWN, on Behalf of Himself X  
and a Class of Persons Similarly Situated, :

Plaintiff, :

v. :

MEDTRONIC, INC.; WILLIAM A. :  
HAWKINS; CAROL A. MCCORMICK; :  
THE QUALIFIED PLAN COMMITTEE :  
OF MEDTRONIC, INC.; THE :  
MEDTRONIC, INC. BOARD OF :  
DIRECTORS COMPENSATION :  
COMMITTEE RICHARD H. :  
ANDERSON; VICTOR J. DZAU; :  
JAMES T. LENEHAN; KENDALL J. :  
POWELL; JACK W. SCHULER; THE :  
MEDTRONIC, INC. BOARD OF :  
DIRECTORS; DAVID L. CALHOUN; :  
ARTHUR D. COLLINS, JR.; WILLIAM :  
A. HAWKINS; SHIRLEY ANN :  
JACKSON; DENISE M. O'LEARY; :  
ROBERT C. POZEN; JEAN-PIERRE :  
ROSSO, and JOHN DOES 1-20, :

Defendants. X

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**CLASS ACTION**

**COMPLAINT FOR BREACH OF  
FIDUCIARY DUTY AND  
VIOLATION OF ERISA  
DISCLOSURE  
REQUIREMENTS**

**JURY TRIAL DEMANDED**

**COMPLAINT**

Plaintiff Mark Brown ("Plaintiff"), on behalf of himself and on behalf of a  
class consisting of similarly situated participants and beneficiaries (the  
"Participants") of the Medtronic, Inc. Savings and Investment Plan (the "Plan"), by

his attorneys, alleges the following for his Complaint (the “Complaint”). The allegations contained herein are based on the investigation of counsel, except for those allegations pertaining to the Plaintiff, which are based on personal knowledge. Plaintiff may, after discovery and/or disclosure proceedings in this case, seek leave to amend this Complaint to add new parties or claims.

### **NATURE OF ACTION**

1. Plaintiff, who was a Participant in the Plan during time periods relevant to this Complaint, brings this civil enforcement action under Section 502(a) of the Employee Retirement Income Security Act (“ERISA”), 29 U.S.C. § 1132(a), for plan-wide relief on behalf of a class consisting of all current and former Participants in the Plan for whose individual accounts the Plan held shares of common stock of Medtronic, Inc. (hereinafter “Medtronic” or the “Company”) (including in the form of units of the Medtronic Common Stock Fund) at any time from February 15, 2007 to November 19, 2007, inclusive (the “Class Period”). Plaintiff brings this action on behalf of the Plan and the Class pursuant to § 502(a)(2) and (3) of ERISA, 29 U.S.C. § 1132(a)(2) and (3). As more fully set forth below, Defendants breached their fiduciary duties to the Participants, including those fiduciary duties set forth in ERISA § 404, 29 U.S.C. § 1104, and Department of Labor Regulations, including 29 C.F.R. § 2550. Defendants breached their fiduciary duties to the Participants in various ways, including, but

not limited to, (i) misrepresenting and failing to disclose material facts to the Participants in connection with the administration of the Plan; (ii) failing to exercise their fiduciary duties to the Participants solely in the interests of the Participants for the exclusive purpose of providing benefits to Participants and their beneficiaries; (iii) failing to manage the Plan assets with the care, skill, prudence or diligence of a prudent person under the circumstances; (iv) imprudently failing to diversify the investments in the Plan so as to minimize the risk of large losses; and (v) permitting the Participants to continue to elect to invest their retirement monies in Medtronic common stock when it was imprudent to do so, and when the Participants were not provided with timely, accurate and complete information concerning the Company as required by applicable law. As a result of these wrongful acts, pursuant to ERISA § 409(a), 29 U.S.C. § 1109(a), Defendants are personally liable to make good to the Plan the losses resulting from each such breach of fiduciary duty. In addition, under § 502(a)(3) of ERISA (29 U.S.C. § 1132(a)(3)), Plaintiff seeks other forms of appropriate equitable relief, including, without limitation, injunctive relief and, as available under applicable law, imposition of a constructive trust, restitution, and other monetary relief. Insofar as any Defendant is sued alternatively as a knowing participant in a breach of fiduciary duty for equitable relief, Plaintiff intends to proceed pursuant to § 502(a)(3) of ERISA (29 U.S.C. § 1132(a)(3)).

### **JURISDICTION AND VENUE**

2. Plaintiff's claims arise under and pursuant to ERISA § 502, 29 U.S.C. § 1132.

3. This Court has jurisdiction over this action pursuant to ERISA § 502(e)(1), 29 U.S.C. § 1132(e)(1).

4. Venue is proper in this District pursuant to ERISA § 502(e)(2), 29 U.S.C.

§ 1132(e)(2), because this is a District where the Plan was administered, where breaches of fiduciary duty took place and/or where one or more Defendants reside or may be found.

### **THE PARTIES**

5. Plaintiff Mark Brown is a resident of the State of Arizona. Plaintiff was employed by Medtronic (or a subsidiary or division of Medtronic) for approximately 24 years from approximately 1974 until approximately 2008, and maintained an investment in Medtronic common stock in his individual account in the Plan during the Class Period.

6. Defendant Medtronic, Inc. is a medical technology company. The Company operates in seven business segments: Cardiac Rhythm Disease Management (CRDM); Spinal; CardioVascular; Neuromodulation; Diabetes; Surgical Technologies, and Physio-Control. The Company is incorporated in Minnesota and maintains its principal place of business at 710 Medtronic Parkway,

Minneapolis, MN 55432. Medtronic is a fiduciary with respect to the Plan.

7. At all times relevant to this Complaint, Defendant William A. Hawkins (“Hawkins”) served as Medtronic’s President and Chief Executive Officer. At all times relevant to this Complaint, Defendant Hawkins acted as a fiduciary with respect to the Plan.

8. At all times relevant to this Complaint, Defendant Carol A. McCormick (“McCormick”) served as Medtronic’s Senior Vice President, Human Resources. At all times relevant to this Complaint, Defendant McCormick acted as a fiduciary with respect to the Plan. Defendant McCormick signed the form 11-K annual reports of the Plan which was filed with the SEC on or about October 24, 2007.

9. At all times relevant to this Complaint, Defendant Qualified Plan Committee (the “Committee”) managed and administered the Plan and the assets of the Plan and acted as a fiduciary with respect to the Plan. The Form 11-K annual report of the Plan which was filed with the SEC on or about October 24, 2007 states that “The Qualified Plan Committee (the “Committee”) of the Parent Company oversees the administration of the Plan.”

10. At all times relevant to this Complaint, Defendant the Medtronic, Inc. Board of Directors Compensation Committee (the “Compensation Committee”) acted as a fiduciary with respect to the Plan. The Charter Compensation Committee

states that “[t]he Compensation Committee assists the Board in carrying out its responsibilities with respect to (a) employee qualified benefit plans and employee stock programs” and lists the duties and responsibilities of the Compensation Committee as including the duty and responsibility “[t]o review the design of and approve the Qualified Benefit Plans and Nonqualified Benefit Plans in performance of the fiduciary duties assigned to the Committee.”

11. Defendants Richard H. Anderson (Chair); Victor J. Dzau; James T. Lenehan; Kendall J. Powell, and; Jack W. Schuler were members of the Compensation Committee during the Class Period. The Compensation Committee and the Compensation Committee Defendants failed to properly appoint, monitor and inform such persons in that the Compensation Committee and the Compensation Committee Defendants failed to adequately inform such persons about the true financial and operating condition of the Company or, alternatively, the Compensation Committee and the Compensation Committee Defendants did not adequately inform such persons of the true financial and operating condition of the Company (including the financial and operating problems being experienced by Medtronic during the Class Period identified herein) but nonetheless continued to allow such persons to offer Medtronic common stock as investment options under the Plan when the market prices of Medtronic common stock was artificially inflated and when Medtronic common stock was not prudent investments for

Participants' retirement accounts under the Plan. Liability is only asserted against the Compensation Committee and the Compensation Committee Defendants for such periods of time as each Compensation Committee Defendant was a member of the Compensation Committee or otherwise acted as a fiduciary with respect to the Plan.

12. At all times relevant to this Complaint, Defendant the Medtronic, Inc. Board of Directors (the "Board") acted as a fiduciary with respect to the Plan. The Charter Compensation Committee states that "[t]he Compensation Committee assists the Board in carrying out its responsibilities with respect to (a) employee qualified benefit plans and employee stock programs" and lists the duties and responsibilities of the Compensation Committee as including the duty and responsibility to "[t]o review the design of and approve the Qualified Benefit Plans and Nonqualified Benefit Plans in performance of the fiduciary duties assigned to the Committee."

13. Defendants Richard H. Anderson; David L. Calhoun; Arthur D. Collins, Jr.; Victor J. Dzau; William A. Hawkins; Shirley Ann Jackson; James T. Lenehan; Denise M. O'Leary; Kendall J. Powell; Robert C. Pozen; Jean-Pierre Rosso, and; Jack W. Schuler (the "Director Defendants") were members of the Board of Directors of Medtronic which was assisted in its Plan-related duties by the Compensation Committee. The Board of Directors and the Director Defendants

failed to properly appoint, monitor and inform such persons in that the Board of Directors and the Director Defendants failed to adequately inform such persons about the true financial and operating condition of the Company or, alternatively, the Board of Directors and the Director Defendants did adequately inform such persons of the true financial and operating condition of the Company (including the financial and operating problems being experienced by Medtronic during the Class Period identified herein) but nonetheless continued to allow such persons to offer Medtronic common stock as investment options under the Plan when the market prices of Medtronic common stock was artificially inflated and when Medtronic common stock was not prudent investments for Participants' retirement accounts under the Plan. Liability is only asserted against the Board of Directors and the Director Defendants for such periods of time as each Director Defendant was a member of the Board of Directors or otherwise acted as a fiduciary with respect to the Plan.

14. John Does 1-20 were the individual members of the Committee and members of any other committee(s) which administered the Plan. The identity of the members of the Committee, and of any other committee(s) which administered, managed, or helped to administer or manage the plan.



### **CLASS ACTION ALLEGATIONS**

15. Plaintiff brings this action on his own behalf and as a class action pursuant to Rules 23(a), (b)(1) and/or (b)(2) of the Federal Rules of Civil Procedure, on behalf of a class consisting of all current and former Participants in the Plan for whose individual accounts the Plan held shares of Medtronic stock (including in the form of units of the Medtronic Common Stock Fund) at any time from February 15, 2007 to November 19, 2007 (the “Class”).

16. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are, at minimum, thousands of members of the Class. In fact, the Form 5500 Annual Return/Report of Employee Benefit Plan for the Plan states that there were 28,039 Participants in that plan as of December 31, 2006.

17. Common questions of law and fact exist as to all members of the Class which predominate over any questions affecting solely individual members of the Class. Among the questions of law and fact common to the Class are:

- a. Whether Defendants were fiduciaries;
- b. Whether Defendants breached their fiduciary duties;
- c. Whether the Plan and the Participants were injured by such breaches; and

d. Whether the Class is entitled to damages and injunctive relief.

18. Plaintiff's claims are typical of the claims of the other members of the Class, as the Plaintiff and all members of the Class sustained injury arising out of Defendants' wrongful conduct in breaching their fiduciary duties and violating ERISA as complained of herein.

19. Plaintiff will fairly and adequately represent and protect the interests of the Class. Plaintiff has retained able counsel with extensive experience in class action ERISA litigation. The interests of Plaintiff are coincident with and not antagonistic to the interests of the other class members.

20. Prosecution of separate actions by members of the class would create a risk of inconsistent adjudications with respect to individual members of the class which would establish incompatible standards of conduct for Defendants, or adjudications with respect to individual members of the class would, as a practical matter, be dispositive of the interests of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests.

21. There are one or more putative or certified class action securities cases pending against Medtronic and other defendants. The claims herein are under ERISA and related principles of federal common law and are not being asserted by the plaintiffs in those other class actions. The named plaintiffs in those class actions do not adequately represent the Plaintiff or the Class herein with respect to

ERISA claims and may be subject to defenses and limitations of liability under the Private Securities Litigation Reform Act (“PSLRA”) and other statutes and rules that do not apply to the claims asserted herein.

22. Under and as required by ERISA, Defendants carry insurance for claims asserted herein that may not be available to the defendants in the securities class actions.

23. The Class in this case contains persons who made purchases of Medtronic common stock within the time frame implicated in the securities class actions, as well as persons who made no such purchases within the class period for the securities actions (*i.e.*, *holders* during the Class period and the class period for the securities actions), and persons who purchased both within and outside the securities class action time frame.

24. There are members of the Class in this case who are not members of the classes or putative classes in the securities class action cases.

#### **DESCRIPTION OF THE PLAN**

25. At all times relevant to this Complaint, the Plan was an employee benefit plan within the meaning of ERISA §§ 3(3) and 3(2)(A), 29 U.S.C. §§ 1002(3) and 1002(2)(A).

26. At all times relevant to this Complaint, the Plan was a “defined contribution” or “individual account” Plan within the meaning of ERISA § 3(34),

29 U.S.C. § 1002(34), in that the Plan provided for individual accounts for each Participant and for benefits based solely upon the amount contributed to the Participant's account, and any income, expenses, gains and losses, and any forfeitures of accounts of other Participants which could be allocated to such Participant's accounts.

27. At all times relevant to this Complaint, the Plan provided a number of different options for investment of the Plan's assets, including Medtronic common stock through the Medtronic Common Stock Fund.

28. At all times relevant to this Complaint, Participants directed the Plan to purchase investments from among the investment options available under the Plan and allocated them to their individual accounts.

29. The Form 11-K Annual Report filed with the SEC by the Plan on or about October 24, 2007, covering the Plan's fiscal year ended December 31, 2004, also states, among other things:

**1. Description of the Plan**

The following description of the Medtronic, Inc. Savings and Investment Plan (the "Plan"), provides only general information. Participants should refer to the Plan document for a complete description of the Plan's provisions.

**General**

The Plan is a contributory defined contribution plan created by Medtronic, Inc. (the "Company"). The Plan

seeks to provide stock ownership benefits and assist employees to increase retirement savings and financial security upon retirement. The Plan has three components: (i) a Supplemental Retirement Plan (“SRP”) component related to participant elective deferrals under Code Section 401(k) and Company cash matching contributions under Code Section 401(m), (ii) an Employee Stock Ownership Plan (“ESOP”) component which included matching contributions for the SRP and non-matching allocations of employer stock until April 30, 2005, and (iii) effective May 1, 2005 a Personal Investment Account (“PIA”) component related to additional employer contributions to a retirement account. Employees must elect to participate in the PIA or they will be automatically enrolled in other Company benefit programs. If employees elect to participate in the PIA, in lieu of benefits under other Company programs, they will receive employer cash contributions to their PIA.

Generally, the Plan is available to all eligible regular full-time and part-time employees immediately upon hire. Eligible employees other than regular full or part-time employees are eligible after performing 1,000 hours of service in a consecutive twelve month period. The Plan qualifies under Section 401(a) of the Internal Revenue Code of 1986, as amended, and is subject to the provisions of the Employee Retirement Income Security Act of 1974, as amended (“ERISA”).

\* \* \*

#### Administration of Plan Assets

The Qualified Plan Committee (the “Committee”) of the Company oversees the administration of the Plan. The Committee appointed Vanguard Fiduciary Trust Company (the “Trustee”) as trustee of the Plan assets. Transactions are executed by the Trustee, as directed by the Committee in its capacity as Plan Administrator. The Trustee has also been appointed as Recordkeeper for the

Plan and to provide participant services, education and communication services. The Trustee maintains a separate account in the name of each participant in the Plan to record the assets allocated to the participant and the earnings and losses thereon, and an allocation of administrative expenses.

**3. Plan's Interest in the Medtronic, Inc. Master Trust<sup>[1]</sup> Fund**

\* \* \*

The financial data of the Medtronic, Inc. Master Trust Fund is as follows:

**Medtronic, Inc. Master Trust Fund  
Statements of Master Trust Assets  
(in 000's)**

	<u>April 30,</u>	
	<u>2007</u>	<u>2006</u>
Investments at fair value:		
Medtronic, Inc. common stock	\$1,102,213	\$1,150,145
Guaranteed investment contracts	<u>287,972</u>	<u>242,134</u>
Medtronic, Inc. Master Trust Fund assets, at fair value	1,390,185	1,392,279
Adjustment from fair value to contract value relating to fully-benefit responsive investment contracts	<u>5,281</u>	<u>6,858</u>
Medtronic, Inc. Master Trust Fund assets	<u>\$1,395,466</u>	<u>\$1,399,137</u>

\* \* \*

The Plan's 11-k also represents:

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<sup>1</sup> The Master Trust contains the assets of both Plans.

**Medtronic, Inc. Savings and Investment Plan**  
**Schedule H, line 4i – Schedule of Assets (Held at End of Year)**  
**April 30, 2007**  
**(in 000's)**  
**\* \* \***

Total Plan investments, excluding the Plan's interest in the Medtronic, Inc. Master Trust Fund	\$ 1,150,145
Plan's interest in Medtronic, Inc. Master Trust Fund	\$ 1,366,791
[Total Assets]	\$ <u>2,869,616</u>

30. The Form 11-K Annual Report filed with the SEC by the Plan thus represents that approximately \$1,150,145,000 of the Plan's total assets of \$2,869,616,000, or approximately 40% of the Plan's assets, were invested in the Medtronic, Inc. Master Trust Fund<sup>2</sup> of April 30, 2007.

31. If Defendants had made full disclosure to the Participants of Medtronic's true operating condition, including the correct concealed information and the Company's volatility to potentially immediate FDA action, the Participants would not have chosen Medtronic common stock as an investment option under the Plan to the extent that they did. Indeed, had the truth been disclosed to the Participants, Medtronic common stock would not have been chosen by many of the Participants as an investment option at all.

32. The 11-K also states that "Participants are also limited to two transfers

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<sup>2</sup> The Forms 11-k show that 83% of the Medtronic Master Trust Fund was invested in Medtronic common stock.

per month in or out of the Medtronic Common Stock Fund (which is included in the Medtronic, Inc. Master Trust Fund).”

### **ADMINISTRATION OF THE PLAN**

33. Defendants, as fiduciaries of the Plan, were required by ERISA to furnish certain information to Participants. For example, ERISA Section 101 (29 U.S.C. § 1021) requires the Plan’s Administrator to furnish Summary Plan Descriptions (“SPD”) to Participants. ERISA Section 102 (29 U.S.C. § 1022) provides that an SPD must apprise Participants of their rights and obligations under the Plan.

34. At all times relevant to this Complaint, Defendants had the discretion to establish and change the investment alternatives among which Participants could direct the investment of the Plan’s assets allocated to their accounts.

35. At all times relevant to this Complaint, Defendants had a duty to review the Plan’s investment policies and the selection and the performance of investment alternatives offered under the Plan. There was no requirement that any assets of the Plan be invested in Company stock or that Company stock be continued as an investment alternative.

36. At all times relevant to this Complaint, Defendants had a duty to obtain from the Company information necessary for the proper administration of the Plan.



37. At all times relevant to this Complaint, Defendants were fiduciaries of the Plan as defined by ERISA § 3(21)(A), 29 U.S.C. § 1002(21)(A), because they exercised discretionary authority or control respecting management of the Plan or exercised discretionary authority or control respecting management or disposition of assets and had discretionary authority or responsibility in the administration of the Plan.

38. Each Defendant is liable for the breaches of fiduciary duty of the other Defendants under ERISA § 405, 29 U.S.C. § 1105.

#### **BREACHES OF FIDUCIARY DUTY**

39. As required by ERISA, Defendants issued one or more SPDs, each of which either referred to or incorporated by reference the documents filed by Medtronic with the SEC under the federal securities laws. These filings, however, contained numerous material misrepresentations and omitted to state material facts which were necessary to make the statements which were made not misleading.

40. Medtronic's SEC filings during the Class Period, as incorporated into the SPDs, negligently omitted to disclose to the Participants important information concerning the Company's business, operations, regulatory compliance and prospects. Among other things, the SEC filings and SPDs failed to disclose, and Medtronic stock was an imprudent retirement because of the facts that:

- a. the Company was suffering from longstanding deficiencies in its

quality practices which jeopardized its compliance with applicable FDA regulations;

b. the Company was consistently out of compliance with FDA medical device regulations governing quality practices;

c. the Company was experiencing regulatory problems involving its Sprint Fidelis (the “Fidelis” or “Fidelis lead”) defibrillator lead, one of its most popular products;

d. the Company’s deficiencies in internal controls and failures to comply with FDA medical device regulations jeopardized the safety and efficacy of its Fidelis lead;

e. the Company lacked adequate management controls to ensure that an effective quality system existed as required by FDA regulations;

f. because of the foregoing, the Company was at serious risk throughout the Class Period of civil suits and adverse FDA regulatory, including possibly product seizure, injunctions and civil penalties;

g. the Company’s reputation suffered significant harm because of the above.

41. Defendants were not obligated by ERISA or by the Plan to discharge their duty to provide information to Participants through the mechanism of incorporation of SEC filings. Defendants could have fulfilled this duty by setting

forth sufficient and accurate information in the SPDs themselves, and updating such information as appropriate. Defendants chose, however, to adopt the mechanism of incorporation of SEC filings into the SPDs, and the SEC filings contained materially false and misleading information which caused loss to the Plan and the Participants as set forth above.

42. At all relevant times, Defendants should have known of the material misrepresentations and omissions, including those filed with the SEC and incorporated by reference in the SPDs.

43. Defibrillators are devices that apply sharp electrical shocks to the heart when its beating becomes dangerously rapidly or chaotic. The shocks can restore normal heart rhythms before the malfunctioning heart suffers sudden cardiac arrest, a seizure than can lead to death within minutes.

44. Implanted defibrillators have become a multibillion dollar business for medical device makers following clinical trials showing that they could save thousands of lives annually among patients with weak or damaged hearts who are at heightened risk of sudden cardiac arrest. They consist of small battery-powered canisters implanted into muscle under the collarbone (usually on the right side for left-handed patients and the left for those who are right-handed), which are connected to the heart by insulated wires known as leads.

45. The leads are used both to sense when the heart is experiencing a

rhythm that requires a shock and to deliver the shock. Defibrillator canisters need to be replaced when batteries are depleted -- currently every four to seven years -- but leads are left in place unless fractures or infections require them to be removed

46. In September of 2004, the FDA approved the use of the Fidelis lead internal defibrillator, a Medtronic product which became very popular.

47. In early 2007, Medtronic was considered to be “the dominant player” in the defibrillator market. It held a greater than 50% market share against competitors Boston Scientific and St. Jude.

48. However, the data from the first thirty months of its use show that Fidelis leads broke at a higher rate than competing leads. As reported by the Wall Street Journal published on October 30, 2007 entitled “Medtronic Recall Exposes Gaps In Medical Safety --- Spotty Data and Testing Left FDA in the Dark; Firm Cites Five Deaths” (the “Recall Article”), “2.3% of the implanted leads have malfunctioned over a 30-month period studied by Medtronic since the device's introduction in the fall of 2004. Most of these thousands of malfunctions are fractures” which “was higher than the 0.9% rate for one of its Quattro models.”

49. The Recall Article further noted that by early 2007, about 90% of new Medtronic defibrillators used Fidelis leads. Some 268,000 of the devices had been implanted in people around the world, and about 235,000 remain in patients' chests. The leads have brought in about \$1 billion in revenue for Medtronic, which has

annual sales of more than \$12 billion.

50. The Defendants were, or at the very least should have been, aware that the Fidelis lead was defective by February of 2007. On February 15, 2007, the start of the Class Period, and when Defendants should have been or were aware of problems with the Fidelis lead, the price of Medtronic common stock closed at \$54.06.

51. As the Recall Article states:

Like other leads made by Medtronic and its competitors, the Fidelis leads occasionally broke. But the issue went largely unnoticed until those two patients walked into the Minneapolis Heart Institute's pacemaker and defibrillator clinic, in January.

In both cases, doctors at the clinic determined that the patients' Fidelis leads had fractured and misfired. It worried Linda Kallinen, the clinic's technical director. "We wondered if this was happenstance, or not," she says. Adrian K. Almquist, the doctor who treated the patients, found the cases odd because the fractures had occurred within roughly two years of implant.

Scouring electronic logs of other clinic patients, Ms. Kallinen found reports of four other Fidelis fractures in the previous seven months. She and Dr. Almquist went to Robert G. Hauser, a senior consulting cardiologist at the Heart Institute who has made a career of studying defects in heart devices.

In 2005, Dr. Hauser, 68 years old, was instrumental in triggering the recalls of more than 200,000 defibrillators and pacemakers made by Guidant Corp., now part of Boston Scientific Corp. Eight years ago, he organized

other cardiologists to create a private database of failures in defibrillators, pacemakers and leads.

After hearing from Ms. Kallinen and Dr. Almquist, Dr. Hauser combed through his multihospital database. He found similar *trends of fractures in that database as well as multiple Sprint Fidelis lead failures in a separate federal database*. The Heart Institute decided to stop implanting the Fidelis leads altogether and substitute an older Medtronic lead that appeared to be safer, the Sprint Quattro.

Dr. Hauser contacted Medtronic. *In February, he and several other clinic physicians met at the Heart Institute with Warren Watson, a Medtronic vice president, and an engineer. Dr. Hauser says he told Mr. Watson that Medtronic had a serious problem with its Fidelis lead. Three identical device defects at one hospital, he argues, can signify a broader problem.*

(emphasis added).

52. Dr. Hauser submitted an article to the medical journal *Heart Rhythm* on February 22, 2007 (Hauser RG, *et al.*, Early Failure of Small Diameter High-Voltage Inflammable Cardioverter-Defibrillator Lead, *Heart Rhythm*, July 2007: 4 (7), 892-896) concluding that

*The Sprint Fidelis high-voltage lead appears to be prone to early failure. Its use should be limited until the failure mechanism is identified and corrected.* Patients should be evaluated quarterly, and automatic lead test features should be enabled. While more data are needed, routine prophylactic replacement of intact, normally functioning Sprint Fidelis leads does not appear justified.

(emphasis added).

53. The article also notes that the FDA's Manufacturer and User Facility

Device Experience (“MAUDE”) database, an online repository containing information on medical devices malfunctions resulting in serious injury or death showed 679 reports for the Fidelis and “the most frequent complaints were fracture and inappropriate shocks”, one associated with a patient death.

54. The study further concluded the Fidelis was “significantly less reliable” than Medtronic’s Quattro lead and that the incidence of failure in the Fidelis was “1%-2% during the first two years after implant” which was “10-fold greater” than the failure rate of the Quattro. The study stated that the smaller-diameter Fidelis apparently was “less robust and subject to stress damage during and after implant” in comparison to the Quattro.

55. Footnote one of the Hauser article states that he had been communicating with Medtronic about the Fidelis lead data by e-mail no later than February 15, 2007. Footnote three notes that Hauser had been corresponding by mail about the Fidelis lead by the same date.

56. On March 21, 2007, Medtronic sent a “Dear Doctor” letter stating, in essence, that errors with the Fidelis lead were the fault of the implanting doctors. The letter stated:

Dear Doctor,

Medtronic has received reports from a limited number of implanting physicians indicating they have experienced higher than expected conductor fracture rates in their

centers with Sprint Fidelis leads. ***While current overall Sprint Fidelis performance is consistent with other leads***, Medtronic is actively investigating these reports, has reviewed them with our Independent Physician Quality Panel, and would like to share ***what we know at this time***.

Through detailed assessment of reported fractures, we have identified two primary locations where conductor fractures have occurred: 1) distal portion of the lead and 2) near the anchoring sleeve tie down. The distal conductor fractures affect the anode (ring electrode) and fractures that occur around the anchoring sleeve affect the cathode (helix tip electrode). Fractures at both locations appear to present clinically as over-sensing, increased interval counts and inappropriate shocks. Medtronic has worked closely with physicians who have experienced fractures and conducted significant bench testing in an attempt to reproduce the fractures and identify root cause. At this point, our investigation suggests that variables within the implant procedure may contribute significantly to these fractures.

For distal conductor fractures, our investigation has identified severe bending or kinking of the distal end of the lead over the lead body while passing through tortuous vasculature as a significant contributing factor. If the lead is severely bent or kinked at the distal end, the conductor may be compromised such that the conductor may fracture after implant due to chronic fatigue from natural cardiac motion. The venous structure or pathway, venous access location, length of introducer sheath and lead insertion force are all factors that may contribute to severe bending or kinking of the lead. Medtronic recommends avoiding severe bending or kinking of the lead during implantation. If you encounter excessive resistance resulting in severe bending or kinking while advancing the lead, please remove the lead and return it to Medtronic.



For conductor fractures that occur around the suture sleeve, our preliminary investigation suggests that under certain implant techniques, the lead appears to be exposed to severe bending or kinking in the pectoral area. We are still investigating and actively partnering with physicians to better understand this type of fracture. If excessive kinking or bending is observed during lead suturing and/or pocket formation, Medtronic recommends the lead be re-sutured and/or pocket reassembled per guidelines in the Medtronic lead implant manual. In addition, positioning the anchoring sleeve against or near the vein may be helpful.

Sprint Fidelis lead models 6949, 6948, 6931, and 6930 were market released in the U.S. and internationally in September and October 2004. Performance of model 6949, the Sprint Fidelis lead currently followed in our System Longevity Study, indicated survival is 98.9% at two years. Sprint Fidelis 6949 performance based upon return product analysis shows 99.86% chronic fracture-free survival at two years. Both evaluation methods suggest performance is in line with other Medtronic leads and consistent with lead performance publicly reported by other manufacturers.

57. Medtronic continued to market and tout the success of its Fidelis lead, including noting in its Form 10-K annual report on May 22, 2007, that “growth was aided by continued strong performance of our Sprint Fidelis leads, which were first released in fiscal year 2005. The strong market acceptance of these products reflects CRDM’s continued product innovation as well as an overall expansion of the tachyarrhythmia and heart failure markets due to increasing clinical data that supports the uses of these devices for certain patient populations.”

58. Medtronic continued to ignore and/or downplay problems with its Fidelis lead. As the Recall Article notes:

On July 19, Medtronic officials met again with Dr. Hauser and other physicians at the Heart Institute. ***Dr. Hauser urged Medtronic to stop selling the*** leads. Medtronic's vice president for quality and regulatory issues, Reggie Groves, demurred, using a PowerPoint presentation to show that the incidence of fractures still wasn't statistically significant, according to people present. The company declines to elaborate.

According to the Heart Institute's Ms. Kallinen, Medtronic's Ms. Groves said ***the company had identified a problem and was working on a possible remedy, but had no intention of pulling the leads off the market.***

***The company was trying to get to the bottom of what was becoming a crisis.*** Medtronic says it learned about the five deaths potentially linked to Fidelis leads between August 2006 and this September. The patient study it had begun in 2004 by late July had data on 654 patients, and the separate, eight-month CareLink analysis of 25,000 patients was well under way. Using that information, Medtronic analysts by October determined that the Fidelis overall failure rate -- 2.3% over 30 months on the market -- was higher than the 0.9% rate for one of its Quattro models.

***Medtronic consulted its outside advisory committee of heart doctors, who thought the company had to act. Just after midnight on Oct. 15, the company issued a news release saying it was withdrawing all Sprint Fidelis leads from the world-wide market. The release quoted Mr. Hawkins as saying the recall "is the right thing to do given currently available information."***

59. On October 15, 2007, Medtronic admitted that, "[b]ased on current

information regarding the 268,000 implanted leads, Medtronic has identified five patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor.” The Company withdrew its Fidelis lead from the market. The same day, the FDA issued a notice entitled "Medtronic Recalls Sprint Fidelis Cardiac Leads Questions and Answers for Consumers."

60. An analyst report issued by Stifel Nicolaus & Company on October 15, 2007 termed the recall a “serious blow” to Medtronic and to the “overall” defibrillator market.

61. The market reaction was swift. Medtronic common stock fell from \$56.33 on October 12, 2007 to close at \$50.00 a share on October 15, 2007, a decline of 11.2% on unusually high volume. Medtronic stock continued its decline to \$45.54 on November 7, 2007 on fears that Medtronic would lose defibrillator market share as a result of the recall and that the company would face significant consumer class actions.

62. On October 19, 2007, the Minneapolis Star Tribune quoted Bank of America analyst Glenn Navarro as stating that “[w]e think Medtronic will lose global ICD market share over the next 12 to 18 months” as a result of the Fidelis recall and Deutsche Bank issued a report indicating that Medtronic was likely to lose defibrillator market share to competitor St. Jude, predicting Medtronic’s market share would fall from 52% to approximately 44%. Similarly, on November

2, 2007, Think Equity Partners LLC, issued a report giving a negative outlook on Medtronic shares, stating: “We think [Medtronic’s] ICD market share will steadily decline as practices manage risk” and that “with additional quality issues possible, we believe [Medtronic] shares carry more risk.”

63. On November 19, 2007, the Company issued a press release entitled “” stating in relevant part that

- “*Voluntary Suspension of Fidelis® Lead Significantly Impacted Quarterly Results*”;
- “[t]he Fidelis defibrillator lead recall had an estimated negative impact of \$115 million and \$15 million on ICD and Pacing revenue, respectively. Additionally, CRDM incurred expenses of approximately \$31 million in inventory write-offs and other direct costs associated with Fidelis during the quarter.”
- “Commenting on the voluntary suspension of Fidelis® leads and its negative impact to the business this quarter, Bill Hawkins, Medtronic president and chief executive officer said, ‘This was the right decision as there is nothing more important to us than the safety and well being of patients.’”

(emphasis in original).

64. On November 19, 2007, Medtronic common stock closed at \$45.95 per share as a result of the Fidelis problems.

65. In total, between February 15, 2007 and November 19, 2007, Medtronic common stock decreased \$8.11 per share, or roughly 15%, from \$54.06 per share to \$45.95 per share thereby depriving the Class of a substantial amount of their retirement savings.

### **MISMANAGEMENT OF PLAN ASSETS**

66. Pursuant to ERISA § 404(a), 29 U.S.C. § 1104(a), at all times relevant to this Complaint, Defendants had a duty to discharge their duties with respect to the Plan with the care, skill, prudence and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and of like aims, and to diversify investments in the Plan so as to minimize the risk of large losses, unless under the circumstances it is clearly prudent not to do so.

67. Defendants are not entitled to the protections of ERISA § 404(c), 29 U.S.C. § 1104(c), because the Participants did not exercise independent control over their accounts, because Defendants subjected them to improper influence with respect to the Plan's investments in Medtronic common stock, and because Defendants concealed material non-public information concerning Medtronic that they were not

precluded from disclosing under applicable law.

68. Defendants breached their fiduciary duties in that they should have known the facts alleged above and should have known that the Plan should not have invested in Medtronic common stock during the Class Period.

**FIRST CLAIM: INVESTMENT IN MEDTRONIC COMMON STOCK**  
**(AGAINST ALL DEFENDANTS)**

69. Plaintiff realleges and incorporates herein by reference the allegations set forth above.

70. Pursuant to ERISA § 409(a), 29 U.S.C. § 110(a), any fiduciary who breaches any of the responsibilities, obligations or duties imposed by ERISA § 404 shall be personally liable to make good to the Plan any losses to the Plan resulting from each breach and shall be subject to such other equitable and remedial relief as the court may deem appropriate.

71. Because of the practices described herein, the absence of internal quality controls and other means to assure that the Company's fundamental business operations complied in all respects with applicable rules and regulations, Medtronic common stock was not a prudent investment for the individual accounts under the Plan during the Class Period.

72. Pursuant to ERISA § 404, Defendants had a duty to discharge their duties with respect to the Plan solely in the interests of the Participants and for the

exclusive purpose of providing benefits to the Participants. Defendants' selection, monitoring, and continuation of the investment alternatives under the Plan was subject to the above-described fiduciary duties. By their continuing to offer Medtronic common stock as an investment under the Plan, when Medtronic's true adverse financial condition was being concealed, Defendants breached each of these fiduciary duties.

73. As a consequence of Defendants' breaches, the Plan suffered losses.

74. Defendants are individually liable to make good to the Plan any losses to the Plan resulting from each breach.

75. Pursuant to ERISA § 502(a)(3), 11 U.S.C. § 1132(a)(3), the Court should also award appropriate equitable relief in the form of restitution.

**SECOND CLAIM: MISREPRESENTATION AND NONDISCLOSURE**  
**(AGAINST ALL DEFENDANTS)**

76. Plaintiff realleges and incorporates herein by reference the allegations set forth above.

77. Pursuant to ERISA § 409(a), 29 U.S.C. § 110(a), any fiduciary who breaches any of the responsibilities, obligations or duties imposed by ERISA § 404 shall be personally liable to make good to the Plan any losses to the Plan resulting from each breach and shall be subject to such other equitable and remedial relief as the court may deem appropriate.

78. Pursuant to ERISA § 404, Defendants had a duty to discharge their duties with respect to the Plan solely in the interests of the Participants and for the exclusive purpose of providing benefits to the Participants.

79. Defendants breached these fiduciaries in that they made material misrepresentations and nondisclosures as alleged above. Among other things, Defendants misrepresented the facts that:

- a. the Company's Fidelis lead was suffering from quality control issues;
- b. the Company was experiencing regulatory problems involving its Sprint Fidelis defibrillator lead, one of its most popular products;
- c. the Company's deficiencies in internal controls and failures to comply with FDA medical device regulations jeopardized the safety and efficacy of its Fidelis lead;
- d. the Company lacked adequate management controls to ensure that an effective quality system existed as required by FDA regulations;
- e. because of the foregoing, the Company was at serious risk throughout the Class Period of civil suits and adverse FDA regulatory, including possibly product seizure, injunctions and civil penalties;
- f. the Company's reputation suffered significant harm because of the above.



80. The Participants relied upon, and are presumed to have relied upon, Defendants' material misrepresentations and nondisclosures to their detriment.

81. As a consequence of Defendants' material misrepresentations and misleading omissions, the Plan suffered losses.

82. Defendants are individually liable to make good to the Plan any losses to the Plan resulting from each breach.

83. Pursuant to ERISA § 502(a)(3), 11 U.S.C. § 1132(a)(3), the Court should also award appropriate equitable relief in the form of restitution.

**THIRD CLAIM: DIVIDED LOYALTY (AGAINST ALL DEFENDANTS)**

84. Plaintiff realleges and incorporates herein by reference the allegations set forth above.

85. Pursuant to ERISA § 409(a), 29 U.S.C. § 110(a), any fiduciary who breaches any of the responsibilities, obligations or duties imposed by ERISA § 404 shall be personally liable to make good to the Plan any losses to the Plan resulting from each breach and shall be subject to such other equitable and remedial relief as the court may deem appropriate.

86. Pursuant to ERISA § 404, Defendants had a duty to discharge their duties with respect to the Plan solely in the interests of the Participants and for the exclusive purpose of providing benefits to the Participants.

87. Defendants breached their fiduciary obligations when they acted in

their own interests rather than solely in the interests of the Participants and Beneficiaries.

88. As a consequence of these breaches, the Plan suffered losses.

89. Defendants are individually liable to make good to the Plan any losses to the Plan resulting from each breach.

90. Pursuant to ERISA § 502(a)(3), 11 U.S.C. § 1132(a)(3), the Court should also award appropriate equitable relief in the form of restitution.

**FOURTH CLAIM: MISMANAGEMENT OF PLAN ASSETS**  
**(AGAINST ALL DEFENDANTS)**

91. Plaintiff realleges and incorporates herein by reference the allegations set forth above.

92. Pursuant to ERISA § 409(a), 29 U.S.C. § 110(a), any fiduciary who breaches any of the responsibilities, obligations or duties imposed by ERISA § 404 shall be personally liable to make good to the Plan any losses to the Plan resulting from each breach and shall be subject to such other equitable and remedial relief as the court may deem appropriate.

93. Pursuant to ERISA § 404(a)(1), 29 U.S.C. § 1104(a)(1), the Defendants were required to discharge their duties with respect to the Plan solely in the interests of the Participants with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and

familiar with such matters would use in the conduct of an enterprise of a like character and of like aims, and to diversify investments in the Plan so as to minimize the risk of large losses, unless under the circumstances it is clearly prudent not to do so.

94. Defendants breached these duties in that the Plan invested in Medtronic stock when the price of Medtronic common stock was artificially inflated, and the Plan overallocated assets into Medtronic common stock, thereby failing to diversify assets so as to minimize the risk of large losses.

95. As a consequence of these breaches, the Plan suffered losses.

96. Defendants are individually liable to make good to the Plan any losses to the Plan resulting from each breach.

97. Pursuant to ERISA § 502(a)(3), 11 U.S.C. § 1132(a)(3), the Court should also award appropriate equitable relief in the form of restitution.

**FOURTH CLAIM: BREACH OF THE DUTY TO PROPERLY APPOINT, MONITOR AND INFORM THE COMMITTEE AND MEMBERS OF THE COMMITTEE (AGAINST THE DIRECTOR DEFENDANTS ONLY)**

98. Plaintiff realleges and incorporates herein by reference the allegations set forth above.

99. The Director Defendants had the duty and responsibility to properly appoint, monitor and inform the members of the Committee and/or other persons who exercised day-to-day responsibility for the management and administration of

the Plan and their assets.

100. The Director Defendants failed to properly appoint, monitor and inform such persons in that the Director Defendants failed to adequately inform such persons about the true financial and operating condition of the Company or, alternatively, the Director Defendants did adequately inform such persons of the true financial and operating condition of the Company (including the financial and operating problems being experienced by Medtronic during the Class Period identified herein) but nonetheless continued to allow such persons to offer Medtronic common stock as an investment option under the Plan even though the market price of Medtronic common stock was artificially inflated and even though Medtronic common stock was not a prudent investment for Participants' retirement accounts under the Plan.

101. As a consequence of these breaches, the Plan suffered losses.

102. Director Defendants are individually liable to make good to the Plan any losses to the Plan resulting from each breach.

103. Pursuant to ERISA § 502(a)(3), 11 U.S.C. § 1132(a)(3), the Court should also award appropriate equitable relief, including in the form of restitution.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for:

A. Actual damages in the amount of any losses the Plan suffered, with

such losses to be allocated among the Participants' individual accounts in proportion to the accounts' losses;

- B. Appropriate equitable relief, including in the form of restitution;
- C. Costs pursuant to 29 U.S.C. § 1132(g);
- D. Attorneys' fees pursuant to 29 U.S.C. § 1132(g) and the common fund doctrine; and
- E. Such other relief as the Court may deem equitable and just.

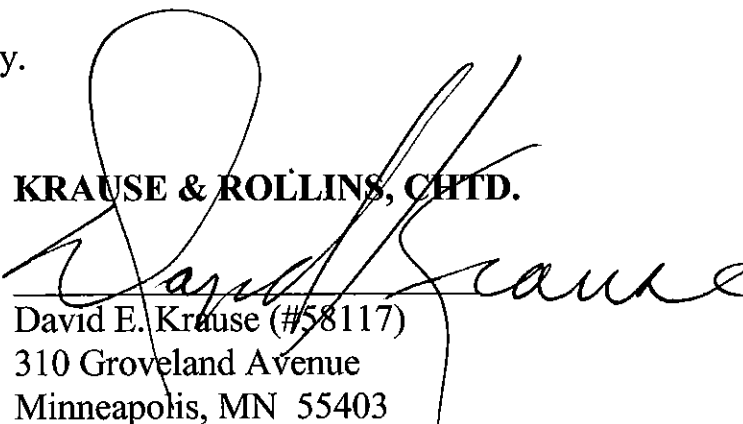
**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

Dated: August 11, 2008

**KRAUSE & ROLLINS, CHTD.**

By:

  
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